

Application Serial No. 09/826,575

P02054US1

**REMARKS/ARGUMENTS**

Applicants and Applicants' Representative express their thanks for the Examiner's availability and consultation on the present case. The following remarks/arguments are intended to supplement those provided in Applicants' previous Response mailed on January 12, 2004.

Claims 1-3, 5-26 and 32-61 are pending in the Application. Claims 4 and 27-31 were previously withdrawn, without prejudice. The following are further remarks/arguments supporting that the invention claimed is non-obvious over the cited prior art. The thrust of these remarks/arguments is directed to the OSHA standard cited by the Examiner and more generally, to the OSHA authority.

First, Applicants direct the Examiner's attention to OSHA issued documents that specifically describes the standard for qualitative fit testing of respiratory protection equipment - the primary use for the smoke tube apparatus claimed (see e.g., 29 CFR 1910.134). To deviate from these specifically prescribed standard would entail legal (safety) and commercial risks. Thus, there is a disincentive (and, lack of motivation) to depart from design that is sanctioned by the appropriate governing body (of particular concern to OSHA, i.e., of course, are the safety and reliability of products). Moreover, the specifically prescribed standard, i.e., design of the smoke tube, has been proclaimed as "State of the Art" by OSHA (see e.g., Preamble to the Proposed Rule, 29 CFR 1910.134, Section III, pg. 4). The closest prior art, the OSHA standard and the related documentation teaches, therefore, away from the design contemplated by the Applicants' invention, which is an indication of non-obviousness. *See e.g., Gillette Co. v. S. C. Johnson & Sons, Inc.* 919 F. 2d 720, 24 (Fed. Cir. 1990) ("the closest prior art reference would likely discourage the art worker from attempting the substitution suggested...")

Furthermore, past OSHA activity and findings provide evidence of secondary considerations, which further support the non-obviousness of the claimed invention. *Graham v. John Deere Co.*, 383 U.S. 1 (1966); Chisum on Patents § 5.02(5). For example, OSHA documents chronicle the intensive effort by the OSHA governing body and industry (i.e., one skilled in the art) to come up with innovations in the state of the art design, prior to the current revised Rule 29 CFR 1910.134. Before this effort, the standard was the glass tube and separate pump combination. This extensive effort did not, however, result in a change.

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The following are excerpts from Section IIA and IIB of the Preamble to the Proposed Rule 29 CFR 1910.134, "Events leading up to the Final Standard":

"On November 15<sup>th</sup>, 1994, OSHA published the proposed rule to revise 29 CFR 1910.134, and announced its intentions to convene an informal public hearing on the proposal (59 FR58884). The informal public hearing was convened on June 6, 1995,...Post hearing submission of data from parties at the hearing were received through September 20, 1995."

"The entire record including 200 exhibits, more than 3,000 individual items and approximately 2,300 transcript pages, was certified by presiding the administrative law judge on June 30, 1997 in accordance with 29 CFR 1911.17".

"Nearly all rule making participants, including representatives of private industry, other Federal Agencies, respirator manufacturers, and unions, agreed that revision is necessary to address these advances (e.g. NISH, Ex: 28; Eastern Chemical Co., Ex 54-245; 3M, Ex 54-218A; AFL-CIO, Ex 54-315; Building and Construction Trades, Department / AFL-CIO, Ex 29; American Petroleum Institute, Ex 37; ISEA, Ex 54-363)".

The OSHA publication reports that "[T]he Standard now reflects current technology and research, as well as, the funding and guidance of other expert bodies". (emphasis added)

Furthermore, OSHA in OSHA's Notice of Proposed Rule Making (NPRM) and Publish Hearing, OSHA 29 CFR 1910, Docket No. #59: 58884 states: "In developing the Proposed Standard OSHA received and analyzed all of the regulations, documents, and comments described above, as well as, other information the agency has obtained during the development process."

Apparently, after much debate and exploration into new designs, the "state of the art" was proclaimed to be a design that uses a glass tube and separate pump – as before. Nevertheless, the opportunity and the motivation were available to others skilled in the art to come up with a new design including Applicant's invention, but these skilled artisans failed to even propose or contemplate a design similar to Applicants' invention. Such "failure of others" in the face of "long felt need" is an indication of non-obviousness. *Graham v. John*

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*Deere Co.*, 383 U.S. 1 (1966); Chisum on Patents § 5.02(5). It should be further noted that, as the Examiner recognizes, there are certain potentially obvious advantages provided by the invention; yet, the public failed to come up with the invention or a structure substantially similar to it.

Moreover, as yet an additional consideration and evidence of non-obviousness, Applicants point out that the benefits of polymer over glass has been known for quite some time. Further, it has been fifty years since the introduction of the glass smoke tube and separate pump combination. The motivation and the disadvantages of this design, as the Examiner recognizes, has been known and much discussion and debate have been focused on the design and its shortcomings. Yet, this long felt need for an alternative design has never been satisfied.

"The existence of an enduring, unmet need is strong evidence that the invention is novel, not obvious, and not anticipated. If people are clamoring for a solution, and the best minds do not find it for years, that is practical evidence – the mind that can't be bought from a hired expert, the kind that does not depend on fallible memories or doubtful inferences – of the state of knowledge." *In re Mahurcar Patent Litigation*, 831 F. Supp. 1354, 1377-78 (N.D.ILL. 1995), aff'd 71 F. 3d 1573 (Fed. Cir. 1995).

Additionally, the Applicants' note that there is an extensive commercial market for smoke tubes, particularly a low-cost design according to Applicants' invention. It is Applicants' experience and belief that the demand for smoke tubes is elastic and price sensitive. Tens of thousands of smoke tubes are sold every year. This large commercial market and the cost savings attributable to Applicants' design, provides yet another motivation for changes in what is otherwise a less than satisfactory state of the art design. The reason that the alternative has not been presented for commercial use is that it is non-obvious.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

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Applicant believes no additional fees are due with this submission. However, if an additional fee is due, please charge our Deposit Account No. 50-0997, under Order No. STDL-P02054US1 from which the undersigned is authorized to draw. Moreover, if any other Petition is required or if the appropriate Petition for Extension of Time does not accompany this Response, applicant hereby applies for said Petition and authorizes any fee associated therewith.

The undersigned is available for consultation at any time, if the Examiner believes such consultation may expedite the resolution of any issues.

Dated: 03/17, 2004

Respectfully submitted,

By AQJ  
Alberto Q. Amatong, Jr.  
Registration No.: 41,580  
The Morris Law Firm, P.C.  
10260 Westheimer, Suite 360  
Houston, Texas 77042  
(713) 334-5151  
(713) 334-5157 (Fax)  
Attorneys for Applicant